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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/798,794	03/11/2004	Jesse W. Hartley	GUID.128PA (03-079)	5634

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EXAMINER

MORALES, JON ERIC C

ART UNIT	PAPER NUMBER
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3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/798,794

Applicant(s)

HARTLEY ET AL.

Examiner

Jon-Eric C. Morales

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date See Continuation Sheet.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/4/2006 and 2/16/2005 and 3/3/2005.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1-36 are rejected under 35 U.S.C. 102(a) as being anticipated by Park et al. (US 20030153954).

With respect to claim 1 and 31, Park discloses a device that obtains cardiac intervals between cardiac beats, finds the first indicated pacing interval (update atrial rate 608) based on a previous pacing value (overdrive rate 604) and a time period of a cardiac interval (tracked rate in step 606), and uses this to pace the heart with a dynamic overdrive pacing (see figure 6 and sections 0092-0098).

Regarding Claims 2, 23, and 32, Park shows that the cardiac stimulation device initiates delivery of the disordered breathing therapy based on the detection of episodes of sleep apnea (disordered breathing). The detection is based on impedance sensor for respiratory parameters (see figure 2, 3, 5 and section 0041).

With respect to claims 3, 26, and 33, Park discloses that the stimulation device (see figure 2, 3, 5) may activate a pacing method once the patient begins sleeping. The device is predicting that the patient will have a sleep apnea episode and to prevent it from occurring the device is set at a pace to prevent the episode (section 0039).

Regarding claims 4, 12, 13, and 28, Park discloses that ventricular and bi-ventricular overdrive pacing may be used as a therapy for disordered breathing. The rate of ventricle to ventricle (V-V) is reduced to increase pacing rate (bi-ventricular). Another way is to reduce the atrial to ventricle rate (A-V) to overdrive the pacing of the heart (ventricular). The values of A-V and V-V rates are obtained in order for the system to aid in the disordered breathing therapy. The therapy provided is ventricular pacing (section 0096-0097).

Regarding claims 5, 11, and 27, Park discloses that the medical device uses a technique of overdrive pacing that tracks atrial rate (intervals between atrial beats). This tracking allows for generation of pacing pulses in the atrium to assist in treating disordered breathing (see figure 6 and sections 0091-0093, 0101).

With respect to claims 6 and 34, Park discloses that cardiac pacing is adapted based on the characteristics of the disordered breathing (see figure 3). The sensors look for different signs in that of disordered breathing. A respiration analysis is used to see what changes are needed for the system, to ensure the correct therapy is being used on the patient (sections 0050-0058).

With respect to claims 7-8 and 35-36, Park discloses that as the system uses sensors to determine a suitable heart rate based as therapy is being delivered. The system adapts as the effect of the therapy on the patient and the cardiac values being sensed (see fig 2., section 0039-0049).

With respect to claims 9-10 and 29-30, Park discloses that the cardiac interval duration comprises of a most recent or previous cardiac interval duration (see figure 7).

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The overdrive pacing includes steps that test a base rate value that is previously assigned that is faster than a measure rate, though if pacing is already occurring then the rate is set to be faster than the most recent pacing rate (sections 0102-0105).

Regarding Claims 14 and 15, Park shows that the therapy used to mitigate disordered breathing, i.e. apnea, is that of a pacing rate that is greater than a patient's intrinsic rate (see figure 1a and section 0035). Also what can be used for therapy of a disordered breathing, like that of sleep apnea, is use of a dynamic overdrive pacing. This pacing set a higher heart rate than the resting rate of a patient (see section 0039).

With respect to Claims 16-19, Park discloses that the initiating interval comprises a sensed or paced cardiac beat, as well as the terminating event could be made to be a sensed or paced cardiac beat (see figure 6 and 7). The system as disclosed can be initiated by a paced beat and terminated with a paced beat, initiated with a paced beat and terminated with a sensed beat, initiated with a sensed beat and terminated with a paced beat, or initiated with a sensed beat and terminated with a sensed beat (sections 0022, 0035, 0036, 0045, 0093, 0099, 0103).

Regarding claim 20, Park shows a schematic drawing of the stimulation device that is capable of obtaining cardiac intervals between cardiac beats, finds the first indicated pacing interval based on a previous pacing value and a time period of a cardiac interval, and uses this to pace the heart with a dynamic overdrive pacing (see figures 5 and 6 and sections 0065-0084, 0092-0098).

With respect to claims 21 and 22, Park discloses that system cardiac beats can either paced or sensed beats that aid in pacing the heart to treat disordered breathing (see figure 7, sections 0022, 0035, 0036, 0093, 0099).

Response to Arguments

3. Applicant's arguments filed 12/15/2006 have been fully considered but they are not persuasive.

In response to applicants' arguments regarding claim 1, 20 and 31, examiner finds that Park et al. (US 2003/0153954) does determine an indicated pacing interval by using both cardiac interval duration and a previous indicated pacing interval. Park et al. determines pacing interval by tracking cardiac rate, which include a paced rate, cardiac rate under inhibited pacing or an intrinsic heart depolarization (cardiac interval durations). Over multiple cardiac cycles Park then updates the pacing rate by tracking atrial pacing and any intrinsic depolarization (previous indicated pacing interval) and uniformly decrements the atrial pacing rate for cycles that are not inhibited (Fig. 6 steps 604-608, sections 0092-0098).

Conclusion

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patent and patent application publications are cited and further show the state of the art with respect to cardiac paced disordered breathing therapy in general: US 20030153955

US 5792188

US 4856524

US 6641542

US 6574507

US 6988498

US 6904320

US 20040138719

US 6415183

US 6126611

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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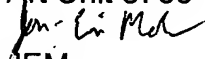
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon-Eric C. Morales whose telephone number is (571) 272-3107. The examiner can normally be reached on Monday through Friday from 8am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call (800) 786-9199 (IN USA OR CANADA) or (571) 272-1000.

Jon Eric Morales
Examiner
Art Unit 3766


JEM


Robert Pezzuto
Supervisory Patent Examiner
Art Unit 3766